

## **REMARKS**

### ***Summary of Changes Made***

The Application was filed with 27 claims. The 27 original claims were canceled and new claims 28 - 52 were added. Claims 42 and 46-52 are canceled herein, and claims 28 and 43 are amended. Accordingly, claims 28-41 and 43-45 (17 claims) remain pending in the application. No new matter is added herewith.

### ***Claim Rejections – 35 U.S.C. § 103(a) (Blum/Watanabe/Hernandez)***

The Examiner rejected claims 28-32, 34-36 and 40-42 under 35 U.S.C. 103(a) as obvious over Blum, et al., U.S. Patent 5,885,600, (“Blum”), in view of Watanabe, et al., “Rotundial a New Natural Mosquito Repellent from the Leaves of *Vitex rotundifolia*,” (“Watanabe”), further in view Hernandez, et al., “Biological activities of crude plant extracts from *Vitex trifolia L. (Verbenacea)*,” (“Hernandez”). The Examiner contends that Blum teaches that insect repellents have long been used to prevent insects from annoying humans and animals and have been used to prevent insect harm to food, clothing and furniture. The Abstract of Blum indicates that an insect repellent can be produced from extracted oils and an antioxidant. Blum further discloses that such products may include additives such as a UV absorber/stabilizer and that antioxidants may include butylates, hydroxytoluene, and ascorboyl palmitate. The extracted oil may be used as an alternative to other repellents and may be formulated into various products for use on humans, animals and vegetation. A variety of insects is listed as the targets of the protection of such products. The Examiner admits that Blum fails to disclose that the repellent is an extract or portion of a *Vitex agnus-castus* plant.

Accordingly the Examiner cites Watanabe for a disclosure that *Vitex rotundifolia* contains a cyclopentadiene aldehyde known as Rotundial, which may be used as a mosquito repellent. Watanabe notes that *Vitex rotundifolia* has been used as a medicinal plant and that parts of the plant are known to repel mosquitoes. Neither Watanabe nor Blum discloses *Vitex agnus-castus*.

Accordingly, the Examiner cites Hernandez for a teaching that the genus *Vitex* includes about 270 known species of plant life of which several species provide various medicinal and

pesticidal activities.

The Examiner finds motivation for the combination of Blum/Watanabe/Hernandez in both Watanabe and Hernandez given the teachings of Blum. The Examiner concludes that the claimed invention is obvious in view of the cited prior art combination and hence unpatentable.

The Examiner will note that claim 42 is canceled herein rendering the rejection thereof moot. Claims 28 and 43 have been amended to recite that the method and composition relates to repelling ticks and mites only, a limitation found in claims 4 and 26 as originally filed.

The apparent connection among Blum, Watanabe and Hernandez is as follows: Hernandez discloses that there are 270 species in genus *Vitex*. Hernandez discloses that certain species of *Vitex* have insecticidal activity. Hernandez discloses the species *Vitex agnus-castus*, (although it does not disclose that *Vitex agnus-castus* has insecticidal activity). Watanabe discloses *Vitex rotundifolia* as an insect (mosquito) repellent. Blum discloses that plant extracts may have a repellent effect against insects. The Examiner appears to be arguing that any plant extract may have a repellent effect against insects, and somewhat more narrowly, that an extract of any species of *Vitex* may similarly have a repellent effect against insects. Neither is supported by a fair reading of the prior art, and neither is relevant to the presently claimed invention, as amended, directed to a method and composition for repelling ticks and mites.

The instantly claimed invention is not obvious in view of the cited references, and would not result from the combination of the same for the following reasons. Briefly, no reference discloses a repellent effect against ticks and mites (arachnids), and no reference discloses that an extract of any species of *Vitex* has a repellent effect against ticks and mites.

The present invention is characterized by two essential features, namely that the method is very effective for repelling against ticks and mites (arachnids), and that the specific plant species *Vitex agnus-castus* is used for obtaining the composition. Applicants note that *Vitex agnus-castus* is completely different form other *Vitex* species, and that the properties of compositions obtained from other *Vitex* species are also completely different from those of the present composition. The properties of one species of *Vitex* cannot be predicted by observation of the properties of another species. Indeed, as noted in the present specification at page 5, lines 25-28, *Vitex agnus-castus* has been known as a remedy for women's gynecological disorders for hundreds of years, but its repellent properties against ticks have been made available by the

inventors for the first time.

As impliedly admitted by the Examiner by the citation of Hernandez, the genus *Vitex* has 270 different species. There are fundamental differences among the many species. For example, *Vitex agnus castus*, *Vitex trifolia* (the subject of Hernandez) and *Vitex rotundifolia* (the subject of Watanabe) cannot be interbred. Rotundial, noted by Watanabe as a mosquito repellent, and cited by Hernandez, has never been found in *Vitex agnus-castus*, but only in *Vitex rotundifolia*.

In general, plants or animals of different species of the same genus may have completely different properties. An example of this is that cocoa can only be obtained from the seeds of *Theobroma cacao*, whereas *Theobroma grandiflorum* does not contain any theobromine and thus cannot effectively be used as cocoa. As a further example, potatoes and tomatoes both belong to the genus *Solanum*. However, the seeds of potatoes, *Solanum tuberosum*, are poisonous when eaten in a raw state, whereas tomatoes, *Solanum lycopersicum*, containing the seeds are delicious and non-poisonous in a raw state.

Ticks and mites, furthermore, are completely different from mosquitoes. Ticks and mites are arachnids (arachnida), whereas mosquitoes are insects (insecta). In particular, arachnids have 8 legs, an undivided body and no wings. Arachnids bite and draw blood for a period of up to 12 days continuously, and when they do, they bite and draw blood from the upper layers of the skin. Arachnids draw blood in all development stages: larva, nymph and adult. They develop in a dry environment and have a lifetime of 3-10 years.

On the other hand, mosquitoes have 6 legs and a body which is divided into three parts with wings. They bite and draw blood for a period of only several seconds, bite directly into blood vessels and only female adults bite and draw blood. Mosquitoes are born in and develop in the water, and their lifetime is only 1 to 2 months.

Based on the stark differences between arachnids and mosquitoes (insects), it cannot be expected that a repellent which is appropriate for repelling insects such as mosquitoes is also effective as a repellent against arachnids such as ticks and mites. Namely, insects recognize their host, e.g. humans, from a distance, up to 100 meters. Consequently, insect repellents are volatile substances, in particular essential oils, which remain on the skin only for a short period.

Cigarette smoke acts in a similar way to repel insects.

On the other hand, ticks do not recognize their host from a distance, but get onto a host

when it comes in contact with the grass or plants on which they are sitting. Only close proximity of the host attracts a tick. Repellents against ticks, therefore, must remain on the skin for a long time. Ticks are not repelled by cigarette smoke.

Known insect repellents, such as lemongrass oil, lemon oil, clove oil or many other etheric (i.e., essential) oils, have no repelling effect on ticks and mites. Chemical insect repellents, in particular the well known DEET, as well as Icaridine, have a very weak effect on ticks. Thus, in commercial repellents against ticks, the active ingredients have to be used in a very high concentration compared to repellents against mosquitoes. In the context of these facts, the prior art has to be evaluated as follows.

Blum discloses insect repellents from cold processed extracted oils and an antioxidant, in particular oils from Neem, Citronella, and Cedarwoods. The focus is on insects (Abstract), although in col. 6, line 20 ticks and mites are mentioned. It is pointed out that, by cold-pressing and addition of antioxidants, the effectiveness of the repellent can be maintained for a long time. As does the instant specification, Blum discloses that essential oils from plants have long been known as insect repellents. The document is completely silent about *Vitex agnus castus* or any species of *Vitex*. The disclosure of Blum is not enabling for a repellent against ticks, as there is no example showing any effect against them. It appears that the citation of Blum stands for the Examiner's apparent belief that any plant extract or essential oil can be used to repel insects.

Hernandez deals with *Vitex trifolia*, which is completely different from *Vitex agnus-castus*, and its antifeeding activity against the corn insect pest *Spodoptera frugiperda* is unrelated to, and not indicative of, any repellent effect. *Vitex agnus-castus* is discussed as being known for treating diarrhea and gastrointestinal affections and having antimalarial, antimicrobial and antifungal properties (page 1, right col.). The document is completely silent about any repellent effect of *Vitex agnus castus*. Genus *Vitex* is generally described as having only insecticidal activity. That any species of *Vitex* has a repelling effect against any organism in general, and against ticks and mites in particular, is neither disclosed nor suggested.

It is known in the art, that insecticidal effect is different from insect repellent effect. An insecticide requires uptake, for example, ingestion, by the insect, which is killed subsequently. An insecticide may actually attract insects. Indeed, the effectiveness of an insecticide would only be enhanced by its attractiveness to an insect. Conversely, a repellent need not be ingested

by an insect; it is enough for an insect to come into contact with a repellent, which thereby causes the insect to move away from a surface treated with the repellent. Such “surface” may include a possible host, such as a human or animal. Thus, substances used as insecticides have a completely different mechanism of uptake and action from repellent substances. Hernandez cites Watanabe, but does not give any indication of a repellent activity of *Vitex agnus-castus* against ticks and mites. Indeed, there is no such disclosure or suggestion in the prior art.

Watanabe discusses the active ingredient of *Vitex rotundifolia*, known as Rotundial, and the examination of its chemical structure as well as the insect repelling properties of Rotundial. It mentions that plant parts of *Vitex rotundifolia* have been used as mosquito repellent. The document is completely silent about *Vitex agnus-castus* and the repellent activity of a composition obtained from this plant against ticks and mites. As noted previously, the characteristics of insect repellents and arthropod repellents are very different; there is no correlation therebetween.

The Examiner has combined references disclosing compositions which work to kill insects, where the compositions come from different plant sources than instantly claimed. The Examiner’s cited references generally disclose plants of genus *Vitex*, and generally disclose insecticides. However, no combination of the cited references would lead the skilled artisan to develop a composition that repels ticks and mites using extracts of *Vitex agnus-castus*. In summary, given the fact that a plant different from that in the prior art is used instantly, and that the repellent activity is against different animal species from those instantly claimed, it cannot be said that the claimed invention is obvious. Based on the foregoing, Applicants respectfully request withdrawal of the rejection.

***Claim Rejections – 35 U.S.C. § 103(a) (Ross/Watanabe/Hernandez)***

Claims 28, 29, 31-34, and 36-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross, WO/98123150 (“Ross”), in view of Watanabe and Hernandez. The Examiner contends that Ross teaches insect repellent formulations containing N,N-Diethyl-m-toluamide (“DEET”), together with water, a film former polymer and an emulsifier-emulsion stabilizer. The Examiner also notes that Ross discloses the possible inclusion of myriad other additives including compositions to treat dry skin conditions and/or to protect the formulation

against microbial contamination. These include emollients, fragrances, preservatives, vitamins, humectants, skin conditioners, antioxidants, sunscreen ingredients such as titanium dioxide and others. Ross teaches that such repellent compositions are useful against insects such as mosquitoes, flies, ticks, wasps, and bees. Ross fails to disclose that the repellent is an extract or portion of a *Vitex agnus-castus* plant. Accordingly the Examiner cites Watanabe and Hernandez as noted above and concludes that the claimed invention is obvious and unpatentable over the combination of Blum/Watanabe/Hernandez.

The Examiner will note that claims 42 and 46-52 have been canceled rendering their rejection moot.

The only apparent connection between Ross and the secondary references Watanabe and Hernandez is the broad statement in Ross that “[a]ny such materials may be included as desired,” referring to the long list of possible additives in the second paragraph of page 7 of the Office Action. It would appear, then, that the Examiner constructs the rejection over Ross/Watanabe/Hernandez from the viewpoint that the plant extracts of Watanabe and Hernandez are mere “additives” to the “main ingredients” of Ross. Further, while Applicants do not dispute that *Vitex agnus-castus* is disclosed in Hernandez, this mere disclosure, without any suggestion that parts or extracts of *Vitex agnus-castus* can be used as a repellent against arachnids such as ticks and mites does not lead one to believe that an arachnid repellent can be obtained therewith. The disclosures of Ross amount to nothing more remarkable than teachings of various ways to emulsify DEET more effectively, DEET being a well known insect repellent. Ross utterly fails to disclose or suggest any plant of the genus *Vitex* and utterly fails to disclose any composition having a repellent effect against arachnids including ticks and mites.

Ross includes a single, erroneous, reference to ticks, in the second sentence of the document. It reads: “Man has long used various chemical agents to reduce attacks by bothersome insects, such as mosquitoes, flies, ticks, wasps, and bees.” Ticks are not insects. The inclusion of ticks in that list of insects is in error, as ticks are arachnids, not insects. The other four members of that list are insects. Indeed, the document is entitled “Insect Repellent Emulsions;” the skilled artisan, reading Ross for all it teaches could only come away with the belief that Ross’ formulations would have no effects on ticks or any kind of arachnids as the focus is on insects. Ross contains no true disclosure or suggestion of arachnids such as ticks or

mites. Therefore, Applicants explicitly state their conviction that Ross is wholly irrelevant to the presently claimed invention, and its citation should be removed from the record, and the instant rejection withdrawn.

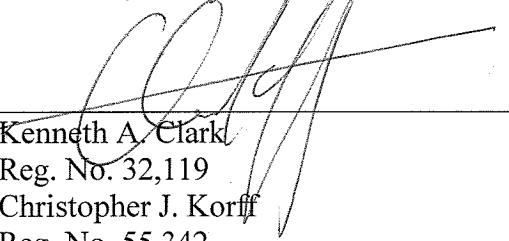
Nevertheless, assuming *arguendo* that Ross is relevant, Applicants state that the combination of Ross with Watanabe and Hernandez is improper. Given that Watanabe discloses and focuses on the drawbacks of DEET, it would seem that a combination of Watanabe with Ross would be discouraged by a fair reading of Watanabe. Based on the foregoing, Applicants respectfully request withdrawal of the rejection.

## **CONCLUSION**

Based on the foregoing, the Applicants respectfully request entry of the instant amendment and a Notice of Allowability for claims 28-41 and 43-45. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application. If there are any additional fees resulting from this communication, please charge the same to our Deposit Account No. 18-0160, our Order No. GIL-16108.

Respectfully submitted,

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